



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2021-0001]

Eligibility of Lithuania to Export Egg Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it intends to list Lithuania as a country eligible to export egg products to the United States. FSIS has reviewed Lithuania's laws, regulations, and documents concerning their egg products inspection system, audited the system as implemented, and determined that Lithuania's egg products inspection system is equivalent to the system that the United States has established under the Egg Products Inspection Act (EPIA) and its implementing regulations. Should FSIS make a final determination to list Lithuania as eligible to ship egg products to the United States, only egg products produced in certified Lithuanian establishments would be eligible for export to the United States. All such products would continue to be subject to re-inspection at U.S. points-of-entry by FSIS inspectors. FSIS is requesting comment before it makes a final determination concerning Lithuania's equivalence for egg

products. FSIS will announce its final determination in a subsequent **Federal Register** notice.

DATES: Comments must be received on or before (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER).

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW., Mailstop 3758, Washington, DC 20250-3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW., Jamie L. Whitten Building, Room 350-E, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2021-0001. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to

<https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 205-0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW., Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, telephone (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is announcing that it intends to list Lithuania as a country eligible to export egg products to the United States. Lithuania is currently eligible to export processed beef and pork to the United States.

Statutory and Regulatory Basis for Action

The EPIA prohibits the importation of egg products capable of use as human food into the United States unless they were processed under an approved inspection system of the government of the foreign country of origin and are labeled and packaged in accordance with, and otherwise comply with, the standards of the Act and regulations issued thereunder applicable to such articles within the United States (21 U.S.C. 1046(a)(2)). The regulatory requirements for foreign countries to become eligible to export egg products to the United States are provided in 9 CFR 590.910(a).

Section 590.910(a) requires a foreign country's inspection system to be authorized by a legal authority that imposes requirements equivalent to those of the United States, specifically with respect to labeling, packaging, sanitation, processing, facility requirements, and Government inspection. The foreign country's inspection system must ensure that establishments preparing egg products for export to the United States comply with requirements equivalent to those of the EPIA and the regulations promulgated by FSIS under the authority of that statute. The foreign country is required to certify establishments as having met the required standards and to notify FSIS of those establishments that are either certified or removed from certification.

Before the foreign country can export egg products to the United States, FSIS needs to evaluate the country's inspection system for egg products to determine whether it is equivalent to FSIS', and therefore, eligible to export egg products to the United States. This evaluation consists of two processes: A document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program (9 CFR 327.2(a)(2)(iii), 381.196(a)(2)(iii), and 590.910(a)). FSIS requests that countries provide information about their

inspection systems through the Self Reporting Tool (SRT).¹ The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems. Through the SRT, FSIS collects information on practices and procedures in six areas, known as equivalence components: (1) Government Oversight (e.g., Organization and Administration, Enforcement Authority, Government Inspection Personnel-Training/Staffing), (2) Government Verification of Food Safety and Other Consumer Protection Requirements (e.g., Humane Handling, Ante-Mortem Inspection, Post-Mortem Inspection, Product Standards and Labeling), (3) Government Sanitation Verification, (4) Government Hazard Analysis and Critical Control Point (HACCP) Systems Verification, (5) Government Chemical Residue Programs, and (6) Government Microbiological Pathogen and Process Control Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an on-site review is scheduled using a multidisciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS website at

¹ The SRT template can be found on the FSIS website at <https://www.fsis.usda.gov/sites/default/files/import/srt.pdf>.

<https://www.fsis.usda.gov/inspection/import-export/equivalence>.

FSIS regulations (9 CFR 590.910(b)) provide that a list of countries eligible to export egg products to the United States be maintained at <https://www.fsis.usda.gov/importlibrary>. Once listed, the government of an eligible country certifies to FSIS that establishments that wish to export egg products to the United States are operating under requirements equivalent to those of the United States. To verify that products imported into the United States are not adulterated or misbranded, FSIS reinspects all product imported under FSIS jurisdiction and samples a subset of those products for pathogens and residues at points-of-entry before they enter U.S. commerce, as discussed in more detail below.

Evaluation of Lithuania's Egg Products Inspection System

In November 2014, the government of Lithuania requested approval to export egg products to the United States. FSIS conducted a document review of Lithuania's egg products inspection system and concluded, on the basis of that review, that Lithuania's laws, regulations, control programs, and procedures were equivalent to those of the United States.

Accordingly, from October 24, 2016, to November 2, 2016, FSIS proceeded with an on-site audit of Lithuania's egg products inspection system to verify that Lithuania's

State Food and Veterinary Service (SFVS), the central competent authority (CCA) in charge of food inspection, effectively implemented an egg products inspection system equivalent to that of the United States. FSIS audited the SFVS headquarters, one territorial office, and one local inspection office, the single establishment that was to be certified to export egg products to the United States, and the National Food and Veterinary Risk Assessment Institute (NFVRAI), the national government laboratory. During the visit, the establishment was not producing egg products for export to the United States. However, the FSIS auditor was able to conduct observations of SFVS's inspection at the establishment and to verify information that was provided during the document review.

The 2016 on-site audit of Lithuania's egg products inspection system found that SFVS was unable to demonstrate adequate government oversight regarding implementation and verification of its sanitation requirements as evidenced by the establishment's failure to conduct candling procedures and washing, sanitizing, and drying dirty eggs. The FSIS auditors observed that dirty eggs were in direct contact with each other and other eggs on the conveyor and that the establishment's employees were not removing those eggs prior to the breaking operation. In addition, the FSIS auditors observed after the breaking step an accumulation of intact shell eggs or large fragments of broken shells in

the egg products containers, resulting in direct product contamination. Lastly, FSIS auditors observed beaded condensate, dust on overhead structures, and pooling water on the establishment's floor. SFVS responded with its proposed corrective actions for the deficiencies identified during the 2016 audit.

On April 25, 2017, FSIS sent its audit report to SFVS. In the letter accompanying the report, FSIS advised SFVS that as the next step in the review process, the Agency would evaluate SFVS's proposed corrective actions identified during the 2016 audit and would schedule a verification audit in the near future. Additionally, after further assessment of the country's written program, FSIS determined that Lithuania needed to submit updated supporting documentation and to clarify some of the information previously provided to FSIS as part of its initial equivalence request for egg products. Throughout 2018 and 2019, the SFVS continued to provide supporting documents in response to FSIS requests.

From July 15 to July 24, 2019, FSIS conducted an on-site audit to verify whether the food safety system governing egg products was implemented as described in the FSIS SRT and is effective in providing an equivalent level of public health protection as achieved in the United States. Specifically, the audit was intended to determine whether Lithuania's corrective actions in response to the

prior findings were implemented and effective. FSIS audited the SFVS headquarters, two territorial offices, and four local inspection offices, and the one establishment that was to be certified to export egg products to the United States.

The FSIS auditors found that the corrective actions for the 2016 Government Sanitation component findings were implemented and effective in resolving the findings. However, they also determined that the 2016 Government Oversight finding was not resolved and that SFVS was still unable to demonstrate adequate government oversight regarding implementation and verification of its egg products requirements. For example, the government inspection personnel failed to identify several deficiencies at the establishment and could not explain how the egg products pasteurization records presented during the audit supported that pasteurization requirements were met. The FSIS auditors also identified that the establishment was not able to produce a current calibration certificate for one flow rate probe used during the pasteurization process and was not monitoring and documenting product temperature during heat treatment of each lot of dried whites at a supportable frequency. Furthermore, the auditors found that the government inspectors had not identified these noncompliances.

Also, during the 2019 audit, the FSIS auditors observed multiple blood spots on the yolks of multiple eggs with no actions taken by the official government veterinarians or establishment personnel to remove the blood spots or reject the affected egg products. FSIS auditors also identified blocks of yeast used in the fermentation of egg products stored in a refrigerator without any labeling indicating the actual product contents. SFVS responded to FSIS with its corrective actions to the identified deficiencies.

FSIS sent its audit report to SFVS on January 7, 2020. SFVS addressed the FSIS audit findings through corrective action plans presented to FSIS on February 14, 2020 and September 10, 2020. Specifically, veterinarians who perform inspections in egg products establishments were introduced to the FSIS audit findings and the SFVS conducted training on FSIS' egg products training program. The SFVS revised the working procedures to incorporate corrective actions to the audit findings, including instructions on pasteurization requirements. As part of the corrective action plan, the audited egg products establishment installed new pasteurization equipment and an inedible egg rejection system and purchased a replacement flow meter to have on-site while one is being calibrated. The SFVS established requirements for the establishments to include a once per year calibration frequency into their equipment

control program and to label every package of yeast indicating the original name, product manufacturer, shelf life, lot number, and weight. Lithuania also provided documentary evidence to demonstrate adequate function of newly installed equipment and for government inspection activities verifying implementation of corrective actions. FSIS evaluated the corrective action plans and Lithuania's inspection verification activities, based on the information Lithuania submitted, and determined that Lithuania had satisfactorily addressed all the audit findings and was able to meet FSIS requirements and equivalence criteria related to all six components.

On October 29, 2020, FSIS published the final rule, Egg Products Inspection Regulations (85 FR 68640). The rule established new requirements for official plants that process egg products to develop and implement Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedures (Sanitation SOPs) and to meet other requirements, including sanitation performance standards, consistent with FSIS' meat and poultry regulations. On April 15, 2021, FSIS sent a letter to SFVS notifying it of the policy changes and explaining that some requirements for foreign countries had taken effect on December 28, 2020. The letter also stated that the Sanitation SOP requirements would become effective on

October 29, 2021, while the HACCP requirements would take effect on October 31, 2022.

On May 17, 2021, Lithuania provided FSIS with documentation that outlined the changes that were made to the SFVS' egg products inspection system to achieve equivalence with the revised U.S. regulations related to the requirements for establishments to develop and implement HACCP and Sanitation SOPs, including sanitation performance standards. FSIS conducted a document review of SFVS's updated operating procedure and has determined that Lithuania's egg products inspection system is equivalent with the new U.S. regulatory requirements for sanitation and HACCP described in the October 29, 2020 final rule.

In summary, FSIS has completed the document review, on-site audit, follow-up audits with verification of corrective actions as part of the equivalence process and determined that all outstanding issues have been resolved. FSIS has concluded that, as implemented, Lithuania's inspection system for egg products is equivalent to that of the United States. All audit reports on Lithuania's egg products inspection system can be found on the FSIS website at <https://www.fsis.usda.gov/inspection/import-export/international-reports/foreign-audit-reports>.

At this time, Lithuania intends to certify one establishment as eligible to export egg products to the United States. After considering comments in response to

this notice, should FSIS make a final determination that Lithuania maintains an equivalent inspection system, FSIS will publish a subsequent **Federal Register** notice announcing that Lithuania is eligible to export egg products to the United States. In addition, the government of Lithuania would need to certify to FSIS those establishments that wish to export egg products to the United States and that operate in accordance with requirements equivalent to that of the United States (9 CFR 590.510(a)). FSIS would verify that the establishments certified by Lithuania's government are meeting the United States requirements through additional verification audits of Lithuania's egg products inspection system. Although a foreign country may be listed on FSIS' website as eligible to export egg products to the United States, the exporting country's products must be found to comply with all other applicable requirements of the United States. Accordingly, egg products exported from Lithuania would be subject to re-inspection at U.S. points-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS would conduct other types of re-inspection activities, such as taking product samples for laboratory analysis for the detection of chemical residues and pathogens for a subset of Lithuania's egg products imported into the United States. Products that

pass re-inspection would be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they would be refused entry and within 45 days would be exported to the country of origin, destroyed, or converted to animal food (subject to approval of the U.S. Food and Drug Administration), depending on the violation.

Economic Impact Analysis

As explained above, FSIS intends to list Lithuania as a country eligible to export egg products to the United States. Given the limited market in the United States for Lithuania's egg products and Lithuania's projected low export volume, there is likely to be little, if any, impact on the United States economy.

In comparison to the United States, Lithuania is a low volume egg products producer with limited capacity to export egg products. Between 2015 and 2019, Lithuania had an annual average of 3.2 million egg laying hens that produced 55,300 tons of eggs, of which approximately 50,800 tons were consumed within Lithuania. The remaining eggs were exported mainly to the European Union, of which Lithuania is a member. Of these exports, approximately 17.2 percent were in the form of egg products.² As such, FSIS

² Detailed data on Lithuanian egg products is limited. We use the available egg data to estimate the potential amount of egg products Lithuania would be able to export to the United States. Lithuania's production, trade and consumptions data are based on the Food and Agricultural Organization of the United Nations (FAO, 2021) Food Balance Sheet: available at <http://www.fao.org/faostat/en/#data/FBS>. The maximum expected exports potential is based on production plus imports minus consumption and assuming zero ending stock. FSIS calculated 17.2 percent as a five-year average based on 2015-19 FAO data.

estimates the total potential egg products available for export to be approximately 3,200 tons³ (17.2 percent of 18,800 tons). Assuming that the European Union will continue to be Lithuania's largest trading partner, the amount of egg products to be exported to the U.S. is likely to be less than 3,200 tons.

From 2015 to 2019, the U.S. had an annual average of 375 million egg laying hens⁴ that produced 6.6 million tons of eggs, of which approximately 5.6 million tons were consumed domestically.⁵ While the U.S. imports around 11,200 tons of egg products annually, it is a net exporter of egg products.⁶

With only one establishment intending to export egg products to the U.S., Lithuanian egg products exports volume to the U.S. are likely to be low in comparison to the total U.S. egg products market and are expected to have little or no effect on U.S. egg products supplies or their prices. U.S. consumers, however, are expected to enjoy more choices when purchasing egg products.

Effect on Small Businesses

³ Noted that FSIS has jurisdiction over only some egg products, not all.

⁴ U.S. Chicken Layers Inventory are based on USDA National Agricultural Statistics Service (NASS) data for July 1st each year from 2015-19. The data were accessed from the USDA/NASS Quick Stats at: <https://quickstats.nass.usda.gov/results/53032069-6FCE-3AA2-99E7-B33E1C1AD8F2>

⁵ U.S. Production and Consumption Data accessed from USDA/World Agricultural Supply and Demand Estimates (WASDE): <https://usda.library.cornell.edu/concern/publications/3t945q76s?locale=en>. WASDE's egg data are published in dozen; FSIS converted these data into tons using Grade A Large Egg Weight based on USDA/Agricultural Marketing Service conversion rate: accessed from https://www.ams.usda.gov/sites/default/files/media/Shell_Egg_Standard%5B1%5D.pdf.

⁶ U.S. Import and Export Data accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System: <https://apps.fas.usda.gov/GATS/default.aspx>. Egg products are based on Harmonized System (HS) codes 040811, 040819, 040891, 040899, 350211, and 350219.

The FSIS Administrator has made a preliminary determination that this notice will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The trade volume is expected to have little or no effect on all U.S. establishments, regardless of size.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS website located at:

<https://www.fsis.usda.gov/policy/federal-register-rulemaking>. FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations,

directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

USDA Nondiscrimination Statement

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Paul Kiecker,

Administrator